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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,147	09/30/2003	Gilbert R. Gonzales	XANO / 36	5607

26875 7590 11/09/2006  
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CINCINNATI, OH 45202

EXAMINER
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HUH, BENJAMIN

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/675,147

Applicant(s)

GONZALES, GILBERT R.

Examiner

Benjamin Huh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/1/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 & 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims state the usage of a venous blood vessel with respect to positioning of the delivery component but does not necessarily refer back to the fore-mentioned venous blood vessel, therefore the newly mentioned venous blood vessel could be a new blood vessel than the one mentioned before. Also, the delivering medication step states the venous blood vessel and therefore would be indefinite since it would be unknown to which blood vessel "the venous blood vessel" refers to.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5-7, 9-12, & 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) and further in view of Stermann et al (US Patent No. 6699231) or Farley et al (US Patent No. 6401719). The Gonzales reference discloses an infusor system for administering medications in a body

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of a patient comprising a flexible, elongated delivery tube having opposite ends, one of said ends couplable to a supply of liquid medication, said supply being remote from a venous blood vessel; a delivery component, and a pressure altering device, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27. Now, even though Gonzales does not disclose the administration of medication through venous means, more specifically to the pudic veins, attention is directed to Stermann or Farley. The Stermann and Farley references teach the administration of medication through a catheter to the pudic veins also known as the pudendal veins, with respect to Stermann see col. 22 lines 21 – 49, more specifically lines 34-44, & with respect to Farley see col. 23 line 53 – col. 24 line 9 and col. 10 lines 9-12. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Stermann or Farley in the device and method of Gonzales in order to administer the medication to the desired location, such as the pudic veins, for proper treatment. Wherein, the device of Gonzales in view of Stermann or Farley would be fully capable of being placed in confronting relationship with the venous blood vessel so that medication from the supply maybe introduced directly into the blood vessel due to it's size, shape, and ability to work in the environment.

With respect to claims 5-7 & 22, the Gonzales reference discloses a liquid medication and a valve allowing flow, see claims 5 & 6 and col. 4 lines 12-19.

With respect to claims 9-12 & 18-21, the Gonzales reference discloses an increase in intra-abdominal pressure utilizing a binder or restraint, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27.

With respect to claims 16-17, the Gonzales reference discloses the use of an IV bag with a connecting pump, see col. 4 lines 12-19.

With respect to claims 24-26, the Gonzales reference teaches delivering liquid medication to a spinal region of the body, see col. 12 line 28 – col. 13 line 28.

Claims 2-4 & 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) in view of Sterman et al (US Patent No. 6699231) or Farley et al (US Patent No. 6401719) as applied above and further in view of Winchell et al (US Patent No. 5601243). Even though Gonzales does not disclose the delivery component with the venous needle and the medications attention is directed to Winchell. The Winchell reference teaches the use of a venous needle delivering medications, see claim 5, col. 3 lines 3-13, col.5 lines 55-58, and col. 10 line 67- col. 11 line 7. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Gonzales with the teachings of Winchell in order to provide a means for facilitating the piercing and entering of the blood vessel.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) in view of Sterman et al (US Patent No. 6699231) or Farley et al (US Patent No. 6401719) as applied above and further in view of Gordon et al (US Pub No. 2002/0188253a1). Now even though Gonzales does not explicitly disclose a method of administering medication including the initiation of flow of medication and the injection site from the syringe to the tube attention is directed to Gordon. The Gordon reference teaches a method of administering medication, including

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the initiation of flow of medication and the injection site from the syringe to the tube, see claims 16-17 & 20. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to administer the medication in such a manner as to help facilitate the flow for the delivery of the medication.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

The examiner would also like to note that the Declaration filed on 9/1/06 is not effective since it brings up arguments that are not explicitly mentioned in the claims such as the increase of the intraabdominal pressure to cause reversal of blood flow in Batson's Plexus and the drugs being directed to the intraspinal region.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

